Promoting Global Collaboration to Enable Manufacturing Capacity in the COVID-19 Pandemic: ICMRA Pilot for Collaborative Assessment of COVID-19 Related Post Approval Chemistry, Manufacturing and Control (CMC) Changes

This is a high-level proposal aiming to outline the objectives, overview, and deliverables of the collaborative assessment pilot. Further details on the scope and implementation strategy (e.g., type of submissions and engagements among different regulatory agencies) will be further determined with active consultation of the participating regions, once ICMRA Executive Committee endorses this proposal.

OBJECTIVES

- Conduct collaborative quality assessment for COVID-19 related post approval CMC changes including *Post Approval Change Management Protocols (PACMPs)*. The scope of the pilot will focus initially on COVID-19 therapeutics and may be extended to other types of products once more experience is gained. CMC changes subject to the pilot will include, among others, the priorities identified at the ICMRA Industry Virtual Workshop on Enabling Manufacturing Capacity in the COVID-19 Pandemic (e.g., evaluation of information or data on specifications, stability, and/or PACMP that support site changes or additions).
- Identify best practices and standards in the quality assessment of post approval changes including PACMPs.
- Identify misalignments, differences, and potential areas for alignment or harmonization across regions.
- Provide collaboration and dialog opportunities for industry participants who are interested in global filing.
- Build upon and improve the communication and collaboration framework between different regulatory agencies.

PILOT PROGRAM OVERVIEW

The proposed pilot program will use a collaborative assessment framework to identify and exploit areas of alignment between different regulatory agencies in terms of quality assessment for post approval CMC changes including PACMPs. Specifically, the pilot program will focus on COVID-19 related post approval changes that are considered as high priority by many regulatory agencies. Key features of this framework include:

- Facilitating multiple regulatory agencies to take part in a collaborative assessment. It is foreseen that comments and information requests will be shared and discussed prior to external communication with an applicant to achieve better alignment.
- Sharing an applicant's response between the participating regulatory agencies and working towards a common approach to the assessment of responses. This may help to reduce the need

for regulatory agencies to generate multiple independent lists of clarification seeking comments from the applicant.

The purpose of this document is to outline the broad scope of the pilot. The final procedure for how the collaborative assessment will be managed remain to be decided and will be determined in collaboration with participating regulatory agencies. Nonetheless, under the collaborative mechanism, it is foreseen that regulatory agencies can still independently (i.e., without being constrained by other agencies' timelines) issue information requests, but their comments and information requests would be shared and discussed with each other prior to communication with the applicant. This mechanism is expected to provide the necessary flexibility for meaningful discussions on key quality-related areas where misalignment exists and help to streamline the quality assessment of the participating regulatory agencies. It has the potential to increase the alignment between agencies regarding the content of information requests to the sponsor and to benefit external stakeholders.

The duration of the pilot will be one year, which may be extended based on ICMRA members' interest. During this period, the goal is to run collaborative quality assessment for a minimum of three applications with a minimum of three regulatory agencies each time. In case of increased interest from Industry, applications will be selected on the basis of interest for convergence. To ensure feasibility of the pilot, it is foreseen that at start a small number of regulatory agencies (3-5) with any required confidentiality agreements in place will participate in such collaborative assessments, which can then be extended as more experience is gained. Learnings after the pilot will be shared with all ICMRA members.

DELIVERABLES

1. Identify areas of misalignments or differences in quality assessments and create a forum of discussions aiming to promote convergence with concrete learnings and best practices
2. Lessons-learned summaries prepared at the end of each evaluation to share knowledge, provide input on dossier preparation, and inform next steps to improve alignment or harmonization.
3. Proposal for quality assessment guidances and standards, when appropriate.